CLAIMS

16. (twice amended) The tablet of claim 15 wherein the first region and the second region are layers of the tablet, at least one of the layers comprising a coating to provide a protective barrier around the active ingredient in said at least one layer, the protective barrier protecting the susceptible microorganism from the effect of the anti-infective agent.

22. (amended) The formulation of claim 1 wherein said anti-infective agent is selected from the group consisting of betalactams, fluoroquinolones, macrolides, and beta lactamase inhibitors.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Rajiv I. Modi et al. GROUP: 1651

SERIAL NO.: 09/935,099 EXAMINER: Michael V. Meller

FILED: August 23, 2001 DOCKET NO.: CAPH 8016US

FOR: STABLE ORAL PHARMACEUTICAL FORMULATION CONTAINING AN ANTI-INFECTIVE AGENT AND A MICROORGANISM

St. Louis, Missouri
November 7, 2002

Commissioner for Patents
Washington, D.C. 20231

CLAIMS MARKED TO SHOW AMENDMENTS

CLAIMS

1. (amended) A stable fixed dose oral pharmaceutical formulation comprising at least one anti-infective agent as a first active ingredient and at least one microorganism susceptible to said anti-infective agent as a second active ingredient, said anti-infective agent causing significant adverse effects which can be prevented or minimized by said microorganism, at least one of the first and second active ingredients being coated to provide a protective barrier around the active ingredient, the active ingredients being contained in a single pharmaceutical formulation selected from the group consisting of a powder, a tablet, and a capsule, wherein said powder, tablet, or capsule contains both said anti-infective agent and said microorganism, the protective barrier protecting the susceptible microorganism from the effect of the anti-infective agent to maintain the susceptible microorganism in a viable form for a period of at least three months.

2. The formulation of claim 1 wherein said anti-infective agent is selected from the group consisting of Ampicillin, Amoxycillin, Cloxacillin, Clavulanic acid, Sultamicin, Cefuroxime axetil, Cefadroxyl, Cephalexin, Cefixime, Erythromycin, Ciprofloxacin, and combinations thereof.

3. (amended) The formulation of claim 2 wherein said microorganism is selected from the group consisting of Lactobacillus acidophilus, Lactobacillus spores, Lactobacillus lactis, Streptococcus thermophilus, Streptococcus lactis, Saccromyces cerevisea, Lactobacilli GG, and combinations thereof.

4. The formulation of claim 1 wherein the ratio of anti-infective agent to microorganism is in the range of 2:1 to 25:1.

5. The formulation of claim 4 wherein the ratio of anti-infective agent to microorganism is about 5:1.

6. The formulation of claim 1 wherein at least one of the anti-infective agent and the microorganism is coated with a physiologically acceptable excipient to provide granules of the anti-infective agent or the microorganism.

7. The formulation of claim 6 wherein both the anti-infective agent and the microorganisim are coated with an excipient to provide granules of the anti-infective agent and granules of the microorganism.

8. The formulation of claim 7 wherein the anti-infective agent granules and the microorganism granules are formed into a layered tablet such that one layer contains the anti-infective agent and the other layer contains the microorganism.

9. The formulation of claim 6 wherein the excipient is ethyl cellulose.

10. The formulation of claim 6 wherein the excipient is a mixture of microcrystalline cellulose and starch.

11. The formulation of claim 6 wherein the excipient is a mixture of magnesium stearate, polyplasdone XL and sodium chloride.

12. The formulation of claim 1 wherein one of the active ingredients is formed into a coated tablet, and wherein said coated tablet is contained in a capsule containing the other active ingredient.

13. The formulation of claim 12 wherein said tablet contains said microorganism admixed with physiologically acceptable excipients.

14. The formulation of claim 1 wherein the coating comprises a compound selected from the group consisting of cellulose acetate phthalate; poly(butylmethacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methaacrylate); poly(ethyl acrylate, methyl methacrylate); poly(methacrylic acid, methyl methacrylate); poly(methacrylic acid, ethyl acrylate); poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride); hydrogenated Castor oil; Cetyl alcohol; diethyl phthalate; ethyl cellulose; hydroxypropyl cellulose; hydroxypropyl methylcellulose phthalate; and zein.

15. (amended) A stable fixed dose oral pharmaceutical tablet comprising at least one anti-infective agent as a first active ingredient and at least one microorganism susceptible to said anti-infective agent as a second active ingredient, each of the first and second active ingredients forming a discrete part of the tablet such that the first and second active ingredients are physically separated in the tablet and the tablet includes a first region substantially free of the second active ingredient and a second region substantially free of the

first ingredient, the tablet maintaining the susceptible microorganism in a viable form for a period of at least three months..

16. (twice amended) The tablet of claim 15 wherein the first region and the second region are layers of the tablet, at least one of the layers comprising a coating to provide a protective barrier around the active ingredient in said at least one layer, the protective barrier protecting the susceptible microorganism from the effect of the anti-infective agent.

17. The tablet of claim 15, the tablet being coated with an excipient.

18. The tablet of claim 15 wherein at least one of the first active ingredient and the second active ingredient is coated with an excipient to provide granules of at least one of the active ingredients, the granules of at least one of the active ingredients being compressed separately to form a tablet part.

22. (amended) The formulation of claim 1 wherein said anti-infective agent is selected from the group consisting of betalactams, [quinolones] fluoroquinolones, macrolides, and beta lactamase inhibitors.

23. The formulation of claim 1 wherein said anti-infective agent causes diarrhoea, and wherein the microorganism prevents or minimizes diarrhoea induced by the anti-infective agent.

24. The formulation of claim 1 wherein said anti-infective agent is a broad-spectrum antibiotic.